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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
SAIDHA, TEKCHAND				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/839,946

Applicant(s)

WILLIAMS ET AL.

Examiner

Tekchand Saidha

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 07/14/2008 has been entered.
2. Amendment and response to Non-Final Office Action filed 4/2/2009 is acknowledged.
3. Claims 50-61 are pending and under consideration.
4. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn. The reasons are discussed following the rejection(s).
5. New Matter rejection is withdrawn in view of amendment filed 4/2/2009.
6. ***Claim Rejections - 35 U.S.C. § 112*** (second paragraph)

Claims 50-61 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50, line 3, line recites the phrase 'is in a substantially tetrameric form'. The metes and bounds of the claim are not clear and the instant specification does not define the meaning of the term 'substantially' as would be applicable to the 'tetrameric form of the uricase'. Clarification is requested.

Claims 51-61 are included in the rejection for failing to correct the defect present in the base claim.

7. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-53 are rejected under 35 U.S.C. 102(b) as anticipated by Lee et al. [Science 239, 1288-1291 (1988), IDS, previously cited].

Lee et al. (1988) teach the recombinant production of full length amino acid sequence of porcine Urate oxidase (uricase) which is tetrameric and is substantially pure. Mammalian uricase is disclosed as a tetramer with subunit size of 32,000 Daltons (page 1288, column 2, first paragraph after the abstract). The reference further teaches purification to **homogeneity** of Porcine and murine urate oxidase (see, page 1289, second column). Oxidation of uric acid to allantoin is catalyzed by urate oxidase (see abstract). Increased uric acid level, due to lack of this enzyme in man can lead to gouty arthritis (page 1288, column 2). Further, the mammalian uricase of the prior art and the one instantly would therefore be considered the same no matter whether they were isolated from the natural source or were produced recombinantly (claim 52) and that the amino acid sequence (claim 53) being the inherent property of the enzyme would therefore be not patentably distinct.

Claim 50 is directed to 'an isolated tetrameric mammalian uricase, wherein said uricase is in a substantially tetrameric form , and wherein less than 10% of said uricase is in a non-tetrameric aggregated form. Claim 51 depends on claim 50, and the added limitation "wherein the uricase is porcine liver, bovine liver or ovine liver uricase". Claim 52 depends on claim 50, and the added limitation "wherein the uricase is recombinant". Claim 53 depends on claim 52, and the added limitation "wherein the uricase has the sequence of porcine, bovine, ovine or baboon liver uricase".

Claim 50 uses the term "substantially" in defining how much uricase must be in tetrameric form in order to be encompassed within the scope of the claim, and wherein less than 10% of said uricase is in non-tetrameric form. An analysis of the instant Specification to determine whether Appellants have acted as their own lexicographer in defining "substantially." See *Merck & Co., v. TEVA Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1369-70, 73 USPQ2d 1641, 1646 (Fed. Cir. 2005). The review of the Specification, however, does not reveal that "substantially" has been defined in a way different from its ordinary meaning. We thus interpret "substantially" consistent with its ordinary meaning of '*to a great extent or degree*'. We thus interpret the phrase "wherein said uricase is in a substantially tetrameric form" as encompassing a range of uricase or perhaps a greater extent or degree in tetrameric form, with no limit to the range in general and especially with no upper limit" and thus any prior art uricase preparation that contains such an undefined range of the uricase in tetrameric form is encompassed by claim 50. Less than 10% of said uricase is in non-tetrameric aggregated form is interpreted to mean - that 0-10% of said uricase could also be non-tetrameric aggregated.

Lee teaches that porcine liver urate oxidase was obtained commercially and purified to homogeneity, citing footnote 8 (Lee, p. 1289). Footnote 8 states that porcine liver oxidase was obtained from Sigma, and that murine urate oxidase was purified to homogeneity using the method of Conley (1979). Conley (1979) teaches purification of uricase from mammalian tissue by precipitation under certain dialysis conditions (Conley, abstract).

Appellants assert that the Declaration of Merry R. Sherman, Ph.D, filed under 37 CFR § 1.132 and attached as Exhibit D to the Brief, supports their conclusion that "the authors of Lee would not be expected to have produced an uricase preparation in which at least about 90% of the uricase was in a tetrameric form; instead, more than 10% of the uricase would have been present in a non-tetrameric aggregated form." (Br. 12-13 (emphasis in original).) Dr. Sherman at paragraph 5 of the Declaration, referencing the Specification at page 16, lines 5-8, states that "while mammalian uricases *in vivo* (i. e., associated with the peroxisome) exist as a tetramer, isolated purified preparations of

natural and recombinant uricase, as indicated in the present specification and as disclosed by Lee, usually contain a mixture of aggregated non-tetrameric forms of the enzyme, in addition to the tetrameric form."

Page 16, lines 5-8 of the Specification, states:

Purified preparations of naturally occurring and recombinant uricases usually contain a mixture of aggregates of the enzyme, in addition to the tetrameric (140 kDa) form. The percentage of each uricase preparation that is in the tetrameric form generally varies from approximately 20% to 90%.

The Specification, as referenced by the Declaration of Dr. Sherman, thus states that uricase preparations containing up to 90% of uricase in the tetrameric form were known in the prior art. Moreover, as discussed above, claim 50 encompasses uricase preparations containing only approximately 90% of the uricase in tetrameric form.

The claims as amended recites "said uricase to be substantially in tetrameric form" which includes a range of tetrameric uricase(s) and especially with no limit to the range in general and with no upper limit,—falls within the purification to **homogeneity** of Porcine and murine urate oxidase achieved by teachings of Lee et al.

The uricase preparations of claims 50-53 is encompassed by the uricase preparation of Lee et al., and is thus anticipated by the reference of Lee et al.

The reference therefore anticipates the claims.

8. Arguments in the BPAI decision (previously presented):

As per the BPAI decision, affirming Examiner (See page 2 of the decision). The BPAI decision on page 3, paragraph 3 – states: "It is axiomatic that in order for a prior art reference to anticipate the claimed invention, it must disclose every limitation of the claimed invention, either explicitly or inherently. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). We find that Lee, when read in light of Appellants' statement of the state of the prior art as set forth in the Specification, anticipates the claimed subject matter of claim 50. Because our reasoning differs from that of the Examiner, and Appellants have not had a fair opportunity to respond to the rejection, we designate our affirmance as a new ground of rejection. See *In re Kronig*, 539 F.2d 1300, 1302-03, 190 USPQ 425,426-27 (CCPA 1976).

The BPAI decision (page 5, paragraph 3 & 4) citing -

Page 16, lines 5-8 of the Specification, states:

Purified preparations of naturally occurring and recombinant uricases usually contain a mixture of aggregates of the enzyme, in addition to the tetrameric (140 kDa) form. The percentage of each uricase preparation that is in the tetrameric form generally varies from approximately 20% to 90%.

The Specification, as referenced by the Declaration of Dr. Sherman, thus states that uricase preparations containing up to 90% of uricase in the tetrameric form were known in the prior art. Moreover, as discussed above, claim 50 encompasses uricase preparations containing only approximately 90% of the uricase in tetrameric form. Therefore, claim 50 encompasses uricase preparations as prepared in the prior art, such as by Lee, and is thus anticipated by the prior art.

CONCLUSION

In summary, we affirm the rejection of claims 50-53 as being anticipated by Lee. Because our reasoning differs from that of the Examiner, we designate the rejection as to those claims as new grounds of rejection.

9. New arguments:

As may be noted most of the arguments presented here are a repeat of previous arguments. The claim language is changed but Applicants arguments do not address any specific reasons how the amended claim language would overcome the rejections. The claims as amended are broader than claims previously presented and explained in the anticipation rejection, therefore do not overcome the rejection(s) presented here.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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